

Statement of  
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Mr. Chairman and members of the Committee, I am pleased to testify today. My name is Floyd Kvamme. I am co-chair of the President's Council of Advisors on Science and Technology (or PCAST). PCAST comprises a high-level group from academia, industry, and other entities with experience in leading successful science and technology enterprises. My remarks today are my own, but based on our recent review, I am confident that my fellow PCAST members feel similarly on the issues under discussion today.

Last week, PCAST released its second review of the National Nanotechnology Initiative (or the NNI), and I'd like to reference that report in full for this hearing's record. That review, required by Congress as the primary external advisory mechanism for the NNI, includes a detailed assessment of NNI program activities and coordination developed through extensive review and consultation by PCAST members over the last 18 months. The executive summary of the report is attached to this testimony and I recommend it for your review (full report available at: [http://www.ostp.gov/galleries/PCAST/PCAST\\_NNAP\\_NNI\\_Assessment\\_2008.pdf](http://www.ostp.gov/galleries/PCAST/PCAST_NNAP_NNI_Assessment_2008.pdf)).

We are here today to talk about the NNI and the Committee's draft legislation to reauthorize this important interagency research and development (R&D) program. Let me begin by giving you my view of what *nanotechnology* is. If one drops the 'nano' part of the word, we are talking about 'technology'. Technology today invades virtually every part of our economy. It's not only computers and communications, but healthcare, energy, transportation, education, and – in a word – everything. As a result, in talking about a "technology initiative," we are talking about a very wide and varied range of industries and applications. Nanotechnology is simply the continuing development of technology to applications which take advantage of the unique properties of some materials engineered at the nanoscale. Nanotechnology is being applied in virtually all of the applications mentioned above and will, undoubtedly, make many of the products in these applications better – either in performance, cost or both. We should not think of some narrow range of applications for nanotechnology, but rather a vast array of potential uses.

Establishment of the NNI was a very good idea. I commend the great work of Congress and this Committee for formally authorizing this initiative in 2003. In both our first report in 2005 and now our second one released last week, we have had to deal not only with the diversity that is nanotechnology but also a wide range of Federal agencies involved in supporting and/or conducting nano R&D. Appropriately, the initiative did not set up a new agency with a specific budget; rather, it set up coordination, planning, and review mechanisms intended to ensure individual agency activities in nanotechnology are effectively supporting program- and

government-wide goals. I believe recognizing this is important and instructive with respect to the draft legislation, and I'll get to that in a few moments. The legislation did formally establish the coordinating office which raises its budget through contributions from the various agencies with nanotechnology R&D budgets. Agencies with primarily regulatory missions have also taken an active role in the initiative and have contributed to its activities. This strong and deep interagency coordination—a premier example of any such Federal R&D initiative—has been central to the success to date of the NNI.

At the same time, the agencies have specific missions and objective to address. For example, appropriate and informed support for environmental, health and safety (EHS) research within the NNI is an important responsibility that demands strong coordination. With respect to this issue PCAST has found that the NNI's approach has been sound; the interagency coordination process identified EHS research needs, mapped those needs to current activities to identify potential research opportunities, and then prioritized those opportunities to inform budget and planning activities. For example, I refer you to page 49 of the recently-released *NNI Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (full report available at [http://www.nano.gov/NNI\\_EHS\\_Research\\_Strategy.pdf](http://www.nano.gov/NNI_EHS_Research_Strategy.pdf)):

Research Need Agency	Instrument., Metrology, and Analytical Methods	Nanomtl. and Human Health	Nanomtl. and the Environment	Human & Environmental Exposure Assessment	Risk Management Methods	
NIH	○□	◆	□	□		◆ - Coordinating Agency Leadership role in coordinating and communicating with other NNI agencies
NIST	◆	○	○	○	○	
EPA	○□	○□	◆	○□	◆	○ - Contributor Have funded or are planning to fund or conduct research in category
FDA	□	□	□	□	◆	
NIOSH	○□	○□	○	◆	○□	□ - User Have expressed a need for, or expectation to make use of, research outputs or information to support missions & responsibilities
NSF	○	○	○	○	○	
DOD	□	□	○□	□	○□	
DOE	○□	□	○□	□	□	
USDA/CREES	□	○□	○□	□	□	
DOT		□	□	□	□	
OSHA	□	□		□	□	
CPSC	○□	□	□	○□	○□	
USGS	○□		○□	○□		

In this document the Nanoscale Science, Engineering, and Technology Subcommittee's working group on Nanotechnology Environmental and Health Implications (or NEHI) has developed five critical areas for EHS research. The agencies agreed to cooperate such that while there was a lead agency for each task, the other agencies contribute to the overall goals agreed to within the NNI. These efforts do not take away from the other work within the agencies to perform their mission-oriented functions but, in our view, lead to more effective activity within the lead agency. I point specifically to the reports and activities of NIOSH, EPA, FDA, and NIST (detailed on page 27 in our PCAST report) as examples of agency specific activity:

- The OSTP and the Council on Environmental Quality (CEQ) issued in November 2007 a memorandum identifying principles for nanotechnology environmental health and safety oversight based on interagency consensus.<sup>1</sup>

<sup>1</sup> [http://www.ostp.gov/galleries/default-file/Nano%20EHS%20Principles%20Memo\\_OSTP-CEQ\\_FINAL.pdf](http://www.ostp.gov/galleries/default-file/Nano%20EHS%20Principles%20Memo_OSTP-CEQ_FINAL.pdf)

- The National Institute of Occupational Safety and Health (NIOSH) issued a call in July 2006 for information in *Approaches to Safe Nanotechnology*<sup>2</sup> inviting expert feedback from private industry and other government entities, and in June 2007 it issued the report *Progress Toward Safe Nanotechnology in the Workplace*.<sup>3</sup>
- The Environmental Protection Agency (EPA) produced in February 2007 a white paper<sup>4</sup> summarizing the agency's anticipated approach to nanotechnology EHS research, followed in February 2008 by a nanomaterial research strategy.<sup>5</sup> The agency also has launched a Voluntary Nanoscale Materials stewardship program.
- The Food and Drug Administration (FDA) released in July 2007 the report<sup>6</sup> of its Nanotechnology Task Force's efforts to clarify a predictable pathway for application of existing regulatory approaches on a case-by-case basis for developers of nanotechnology-enabled products under its jurisdiction.
- NIST is producing standard reference materials for nanoscale gold and carbon nanotubes.

The provision in the draft reauthorizing legislation that the NNI collectively allocate a minimum of 10% of its nanotechnology R&D to EHS-related research is problematic in both *practice* and *principle*:

- *In practice*, the funding of each agency is fundamentally independent of the NNI. The NSET Subcommittee of the National Science and Technology Council provides the base for coordinating NNI member agencies activities and planning efforts, but it does not direct NNI funding. Furthermore, it is not feasible or reasonable to exclusively designate projects (or portions of projects) as exclusively "EHS" or not. The current reporting structure of the NNI by Program Component Areas or PCAs enables characterization and analysis of the research portfolio that is sufficient for policy and planning purposes. The current funding mechanisms and structure of the NNI makes it difficult for me to see how this "minimum funding" across the program is either reasonable, necessary, or, indeed, practical.
- *In principle*, this set-aside appears to be arbitrary and not based on a sound scientific analysis of the current NNI portfolio of relevant research (including extensive relevant research not reported under the EHS program component area) and what is strategically needed. Instead, support should be guided by the identified gaps and sequential priorities identified in the NNI's nanotechnology EHS research strategy. Like all other aspects of the NNI, EHS research funding decisions should be determined by identified R&D objectives, as is currently the approach of the agencies within the NNI. **Scientifically-determined, strategically-planned priorities—not arbitrary percentages—should guide funding for all nanotechnology research, including research relevant to EHS.**

It is important to note that funding for nano-related EHS research has doubled since 2005. As industry picks up more applications research, the federal government's role will change and is already changing to work more in the EHS and regulatory areas. EHS funding will probably

<sup>2</sup> <http://www.cdc.gov/niosh/topics/nanotech/safenano/>

<sup>3</sup> <http://www.cdc.gov/niosh/docs/2007-123/>

<sup>4</sup> <http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf>

<sup>5</sup> [http://es.epa.gov/ncer/nano/publications/nano\\_strategy\\_012408.pdf](http://es.epa.gov/ncer/nano/publications/nano_strategy_012408.pdf)

<sup>6</sup> <http://www.fda.gov/nanotechnology/taskforce/report2007.pdf>

continue to increase. The one area where funding is accelerating – perhaps tied to our recommendations – is in worker safety where we will propose in our upcoming letter on the EHS report that NIOSH spending accelerate. The reason worker spending is so critical is that in many instances, nanomaterials – while in nano form in the workplace – stop being nanomaterials after production and become a tightly, chemically bound part of a larger system.

With respect to the oversight provisions in the proposed reauthorization, the breadth and depth of high-level expertise of the PCAST in its role as the National Nanotechnology Advisory Panel combined with the detailed expertise of the ad hoc Technical Advisory Group has worked quite well the past five years in providing functional oversight for the NNI and directly advising the President on nanotechnology. The proposed bill should maximize the flexibility for the next Administration in establishing its own advisory structure. As the current PCAST prepares to pass the baton to the next administration, we will suggest they incorporate a similar approach to oversight, leveraging the expertise of a large technical advisory group, whether they be within PCAST or separate.

With respect to overcoming barriers to commercialization and facilitating tech transfer, again I refer to the report of the PCAST review of the NNI. The NNI's unparalleled infrastructure of centers, networks, and user facilities is working very well, geographically distributed and with a wide array of expertise. These facilities are serving their purposes well based on all inputs we have received from both our TAG members and personal experience. Furthermore, the NNI already supports "large-scale research and development projects" on problems of national importance, for example, in energy and biomedicine. The National Cancer Institute, for example, supports a five-year, \$144 million program developing nanotechnology for cancer diagnostics and therapeutics that involves 8 centers and over 400 investigators.

With respect to overall funding, the NNI seems well funded in balance to other programs in the S&T budget. PCAST had hoped that the America COMPETES Act funding would have been passed and will continue to support those priorities of this Congress.

In summary, the NNI as currently structured is a very productive and effective program and a model of interagency coordination. Our newly released report makes recommendations for improvement but finds the program basically sound. Industry is benefiting from its research. A clear strategy has been developed for nanotechnology-related EHS research, and EHS guidelines are being presented to guide industry. International cooperation is happening. The National Nanotechnology Coordinating Office and NNI participating agencies have responded to past recommendations from PCAST as well as the Academies and have strengthened the program. Agencies participate voluntarily because they derive benefit from doing so. A heavy-handed reauthorization with overly prescriptive guidance (like an arbitrary EHS funding floor) and bureaucratic micromanagement (such as costly database requirements) will weaken and inhibit the interagency coordination that is vital to the success of the NNI to date. Rather, this reauthorization should be an opportunity to strengthen and support the interagency coordination founding the NNI, confirming the goals as presented in the original legislation and commending the agencies for their coordinated efforts to maintain the leadership and competitiveness of the U.S. in nanotechnology.



**Appendix:**  
**Executive Summary of**  
***The National Nanotechnology Initiative: Second Assessment and Recommendations of the***  
***National Nanotechnology Advisory Panel*** (April 2008)

The 21st Century Nanotechnology Research and Development Act of 2003 (Public Law 108-153) calls for a National Nanotechnology Advisory Panel (NNAP) to periodically review the Federal nanotechnology research and development (R&D) program known as the National Nanotechnology Initiative (NNI). The President's Council of Advisors on Science and Technology (PCAST) is designated by Executive Order to serve as the NNAP. This report is the second NNAP review of the NNI, updating the first assessment published in 2005.

Including the NNI budget request for fiscal year (FY) 2009 of \$1.5 billion, the total NNI investment since its inception in 2001 is nearly \$10 billion. The total annual global investment in nanotechnology is an estimated \$13.9 billion, divided roughly equally among the United States, Europe, and Asia. Industry analysis suggests that private investment has been outpacing that of government since about 2006. The activities, balance, and management of the NNI among the 25 participating U.S. agencies and the efforts to coordinate with stakeholders from outside the Federal Government, including industry and other governments, are the subject of this report.

The first report answered four questions: How are we doing? Is the money well spent and the program well managed? Are we addressing societal concerns and potential risks? How can we do better? That report was generally positive in its conclusions but provided recommendations for improving or strengthening efforts in the following areas: technology transfer; environmental, health, and safety (EHS) research and its coordination; education and workforce preparation; and societal dimensions.

Since the first report, increasing attention has been focused on the potential risks of nanotechnology, especially the possible harm to human health and the environment from nanomaterials. In this second assessment, the NNAP paid special attention to the NNI efforts in these areas. During its review, the NNAP obtained input from various sources. It convened a number of expert panels and consulted its nanotechnology Technical Advisory Group (nTAG) and the President's Council on Bioethics. NNI member agencies and the National Nanotechnology Coordination Office (NNCO) also provided valuable information.

**The NNAP finds that the United States remains a leader in nanotechnology based on various metrics**, including R&D expenditures and outputs such as publications, citations, and patents. However, taken as a region, the European Union has more publications, and China's output is increasing. There are many examples of NNI-funded research results that are moving into commercial applications. However, measures of technology transfer and the commercial impact of nanotechnology as a whole are not readily available, in part because of the difficulty in defining what is, and is not, a "nanotechnology-based product."

**The NNAP commends and encourages the ongoing NNI investment in infrastructure and instrumentation.** Leading-edge nanoscale research often requires advanced equipment and facilities. The NNI investment in over 81 centers and user facilities across the country that

provide broad access to costly instrumentation, state-of-the-art facilities, and technical expertise has been enormously important and successful. These facilities, which have been funded by many different agencies in order to address a variety of missions, support a diverse range of academic, industry, and government research. In addition, the NNI investment has been used to leverage additional support by universities, State governments, and the private sector.

**Advances in nanotechnology are embodied in a growing number of applications and products in various industries.** Many early applications have been more evolutionary than revolutionary. However, research funded by the NNI today has the potential for innovations that are paradigm shifting, for example in energy and medicine. As with any emerging technology, there is potential for unintended consequences or uses that may prove harmful to health or the environment or that may have other societal implications. The NNAP notes that existing regulations apply to nanotechnology-based products, and those who make or sell such products have responsibilities regarding workplace and product safety. As in 2005, the NNAP believes that the greatest risk of exposure to nanomaterials at present is to workers who manufacture or handle such materials. However, environmental, health, and safety risks in a wide range of settings must be identified and the necessary research performed so that real risks can be appropriately addressed.

**The NNAP views the approach for addressing EHS research under the NNI as sound.** The recent reports by the interagency Nanotechnology Environmental and Health Implications (NEHI) Working Group are good steps by the NNI to prioritize needed EHS research and to coordinate EHS activity across the Federal Government. The NNAP feels that calls for a separate agency or office devoted to nanotechnology EHS research or to set aside a fixed percentage of the budget for EHS research are misguided and may have the unintended consequence of reducing research on beneficial applications and on risk.

In addition to EHS implications, the NNAP considered ethical and other societal aspects of nanotechnology. **In consultation with the President's Council on Bioethics, the panel concluded that at present, nanotechnology does not raise ethical concerns that are unique to the field.** Rather, concerns over implications for privacy and for equality of access to benefits are similar to concerns over technological advances in general. This finding does not diminish the importance of continued dialogue and research on the societal aspects of nanotechnology.

**Overall, the members of the NNAP feel that the NNI continues to be a highly successful model for an interagency program; it is well organized and well managed.** The structure of the interagency Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council effectively coordinates the breadth of nanotechnology activities across the Federal Government. The NSET working groups target functional areas in which additional focus is required. The NNCO provides important support that is a key to the success of the program. The Strategic Plan updated in 2007 clearly communicates the goals and priorities for the initiative and includes actions for achieving progress. With the separation in the updated plan of EHS research from that on other societal dimensions, the NNAP finds the Program Component Areas (PCAs) that are defined for purposes of tracking programs and investments serve the NNI well.

The NNAP has a number of recommendations for strengthening the NNI, which are grouped into six areas.

**1. Infrastructure, management, and coordination.** The NNAP feels that the substantial infrastructure of multidisciplinary centers, user facilities, along with instrumentation, equipment, and technical expertise, is vital to continued U.S. competitiveness in nanotechnology and should be maintained. Whereas the NNAP finds the coordination and management among the NNI participating agencies to be generally strong, intra-agency coordination should be improved, especially in large, segmented agencies. The NNI member agencies should continue to support international coordination through effective international forums, such as the Organisation for Economic Co-operation and Development (OECD). Such efforts will aid in the development of information related to health and safety, as well as addressing economic barriers and impacts. Implementing and monitoring this recommendation should lead to more effective use of agency resources.

**2. Standards development.** Nanotechnology standards are necessary for activities ranging from research and development to commerce and regulation. Federal agencies should continue to engage in national and international standards development activities. The NNI should maintain a strong U.S. representation in international forums and seek to avoid duplicative standards development work. Where appropriate, NIST and other NNI agencies should develop reference materials, test methods, and other standards that provide broad support for industry production of safe nanotechnology-based products.

**3. Technology transfer and commercialization.** The NNI should continue to fund world-class research to promote technology transfer. Strong research programs produce top-notch nanoscale scientists, engineers, and entrepreneurs, who graduate with knowledge, skills, and innovative ideas. Such programs also have the potential to attract more U.S. students to related fields. NNI-funded centers should be structured to spur partnering with industry, which enhances technology transfer. The NNI should seek means to assess more accurately nanotechnology-related innovation and commercialization of NNI research results. These efforts should be coordinated with those of the OECD to assess economic impact of nanotechnology internationally.

**4. Environmental, health, and safety implications.** The NNAP feels that the NNI has made considerable progress since its last review in the level and coordination of EHS research for nanomaterials. Such efforts should be continued and should be coordinated with those taking place in industry and with programs funded by other governments to avoid gaps and unnecessary duplication of work. Moreover, EHS research should be coordinated with, not segregated from, applications research to promote risk and benefit being considered together. This is particularly important when development and risk assessment research are taking place in parallel, as they are for nanotechnology today. The NNI should take steps to make widely available nonproprietary information about the properties of nanomaterials and methods for risk/benefit analysis.

**5. Societal and ethical implications.** Research on the societal and ethical aspects of nanotechnology should be integrated with technical R&D and take place in the context of



broader societal and ethical scholarship. The NNAP feels that this approach will broaden the range of perspectives and increase exchange of views on topics that affect society at large.

**6. Communication and outreach.** The NNAP is concerned that public opinion is susceptible to hype and exaggerated statements—both positive and negative. The NNI should be a trusted source of information about nanotechnology that is accessible to a range of stakeholders, including the public. The NNI should expand outreach and communication activities by the NNCO and the Nanotechnology Public Engagement and Communications Working Group and by coordinating existing agency communication efforts. To enhance effectiveness, the information should be developed with broad input and through processes that incorporate two-way communication with the intended audiences.

This review complements an assessment by the National Research Council (NRC) of the National Academies. The NNAP agrees with many of the NRC recommendations. However, the NNAP questions the recommendation for a formal, independent advisory panel. The panel feels that the current arrangement—whereby the NRC panels of technical experts, the high-level science and technology management leaders of PCAST, and the nanotechnology experts on the nTAG each provide distinct and useful input to the NNI review process—provides a broader perspective than would a single group consisting of a smaller number of advisors.